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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/720,987	TRONO ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-84* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Objections to the Specification

Sequence Compliance

1. The disclosure is objected to because of the following: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Figure 9 contains a nucleotide sequence that is not identified by an accompanying SEQ ID NO:, either in the figure itself or in the brief description of figure 9. Inclusion of the appropriate sequence identifier (i.e., SEQ ID NO:) in the brief description of this figure would be remedial.

The above identification of issues related to Sequence Compliance in the instant Application is by way of illustration. In order to be fully responsive to this Office Action, Applicant should review this application in its entirety to ensure compliance with the requirements of 37 CFR 1.821 through 1.825 and to make all appropriate corrections.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14, 41, 46 and 47, drawn to a polynucleotide construct comprising a region encoding a siRNA operably linked to an externally controllable promoter, an undifferentiated mammalian cell, oocyte or fertilized oocyte comprising a polynucleotide construct in accordance with claim 1, classifiable in class 536, subclass 24.5.

II. Claims 15-40 and 42-45, drawn to a system comprising a polynucleotide construct and a compound or reagent that directly or indirectly controls the expression of the siRNA and a mammalian cell comprising the system, classifiable in class 424, subclass 93.1.

III. Claim 48, drawn to a transgenic animal, classified in class 800, subclass 8+.

IV. Claims 49-51, drawn to a method of making a transgenic animal, classifiable in class 800, subclass 21+.

V. Claims 52-60, 62-71 and 78-84, drawn to a method of regulating the expression of a gene in a cell comprising preparing an siRNA construct of claim 1 that downregulates expression of said gene and externally regulating the expression of the encoded siRNA through the externally controllable promoter, classifiable in class 514, subclass 44.

VI. Claim 61, drawn to a method of testing a drug function by providing a cell comprising a gene silenced by the method of group V and providing said cell a drug for testing drug function, classifiable in class 424, subclass 9.2.

VII. Claims 72-77, drawn to a method of controlling the ability of a cell to be recognized immunologically comprising obtaining a cell comprising an siRNA construct of claim 1 that downregulates expression of a polynucleotide encoding a transplantation antigen and a polynucleotide construct that encodes in inducible repressor capable of repressing the expression of the siRNA construct of claim 1 and externally regulating the expression of the encoded siRNA through the externally controllable promoter, classifiable in class 514, subclass 44.

3. Claim 1 link(s) the patentably distinct inventions identified in Group I. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Claims 15 and 16 link(s) the patentably distinct inventions identified in Group II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 15 and 16. Claim 52 link(s) the patentably distinct inventions identified in Group V that are repressible and

constitutive promoters. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 52. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

4. Groups I, II, III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I is drawn to a polynucleotide construct operably linked to an externally controllable promoter. Group II is drawn to a system comprising a polynucleotide construct operably linked to an externally regulatable promoter and a compound that directly or indirectly controls the expression of the siRNA. Group III is drawn to a transgenic animal. Group VI is drawn to a method of testing drug function by screening

assay. In the instant case, the inventions are not disclosed as capable of use together and have different functions. Invention I functions to provide a polynucleotide construct that expresses an siRNA wherein that expression is under control of an externally controllable promoter. Invention II functions to provide a polynucleotide construct that expresses an siRNA and an agent that directly or indirectly controls the system. Invention III functions to provide a transgenic animal. Group VI functions to provide an assay to screen for a drug that is functional in the absence of a particular polypeptide, the expression of which has been silenced.

Furthermore, searching any of the inventions in groups I, II, III or VI together would impose a serious search burden. In the instant case, prior art searches of a polynucleotide construct, a system comprising a polynucleotide construct and an agent, a transgenic animal and a method of screening for the effect of a drug are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would, for example, require a search for particular compounds or reagents that controlled particular promoters that are limitations of the inventions in Group II that would not be required for a search of the inventions in Group I that are polynucleotide constructs and that would not necessarily be found in a search for the constructs alone. Additionally a search of transgenic animals or a method of screening for the function of a drug would not be coextensive with each other nor with a search of the inventions identified in Groups I or II. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms

of both search and examination. As such, it would be burdensome to perform search and examination of any of Inventions I-III or VI together.

5. Groups III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). Group III is drawn to a transgenic animal and Group IV is drawn to a method of making a transgenic animal using siRNA. In the instant case the product as claimed can be made by another and materially different process which would be introducing a gene construct that coded for a decoy polypeptide operably linked to an appropriate promoter so as to create a transgenic animal capable of exhibiting conditional knockdown of a target gene.

Furthermore, searching Groups III and IV together would impose a serious and undue burden. In the instant case, prior art searches of the transgenic animal and the method of making the transgenic animal, are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, a search for the distinctive steps required by the method that would not be required by a search of for the animal. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both

search and examination. As such, it would be burdensome to perform a search and examination of Groups III and IV together.

6. Groups I and II and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Groups I and II and Group IV are relied upon as above. In the instant case the product as claimed can be used in a materially different process of using that product which would be a method of regulating the expression of a target gene in vitro or a method of treating a subject.

Furthermore, searching Groups I or II and Group IV together would impose a serious and undue burden. In the instant case, prior art searches of a polynucleotide construct or a system for controlling gene expression comprising a polynucleotide construct and another compound or reagent and a method of making a transgenic animal are not coextensive. Search of each of these inventions would require different key word searches of the polynucleotide construct, of the expression system that comprised the polynucleotide construct and the compound or reagent and of the distinctive steps required by the method. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As

such, it would be burdensome to perform a search and examination of any of Groups I and IV together.

7. Groups I and II and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Groups I and II are relied upon as above. Group V is drawn to a method of regulating the expression of a gene in a cell using an siRNA construct that downregulates the expression of the gene. In the instant case the construct of group I and the expression system of group II can each be used in a materially different process of use which would be a method of making a transgenic animal

Furthermore, searching Groups I or II and Group V together would impose a serious and undue burden. In the instant case, prior art searches of a polynucleotide construct or a system for controlling gene expression comprising a polynucleotide construct and another compound or reagent and of a method of regulating gene expression are not coextensive. Search of each of these inventions would require different key word searches of the polynucleotide construct, of the expression system that comprised the polynucleotide construct and the compound or reagent and of the distinctive steps required by the method. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would

then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of any of Groups I and V together.

8. Groups I and II and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Groups I and II are relied upon as above. Group VII is drawn to a method of controlling the ability of a cell to be recognized immunologically using a cell that comprises a polynucleotide construct or an expression system that comprises a polynucleotide construct and a compound or reagent that directly or indirectly controls siRNA expression from the construct. In the instant case the construct of group I and the expression system of group II can each be used in a materially different process of use which would be an assay method of determining the phenotypic response of a cell in vitro to the silencing of a particular gene by comparing cells wherein the expression of the gene was downregulated and unregulated.

Furthermore, searching Groups I or II and Group VII together would impose a serious and undue burden. In the instant case, prior art searches of a polynucleotide construct or a system for controlling gene expression comprising a polynucleotide

construct and another compound or reagent and a method of controlling the ability of a cell to be recognized immunologically are not coextensive. Search of each of these inventions would require different key word searches of the polynucleotide construct, of the system that comprised the polynucleotide construct and the compound or reagent and of the distinctive steps required by the method, with particular regard to the immunological limitations. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of any of Groups I or II and Group VII together.

9. Groups III, V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups III, V and VII are relied upon as above. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Group III operates, as a transgenic animal, to provide a model of a gene knockdown. Group V operates, as a method, to reduce the expression of a target gene in a cell, by expressing, in the cell, an siRNA prepared in a polynucleotide construct. Group VII can operate, as a method, to control the ability of a cell to be recognized immunologically by repressing the expression of an siRNA in a cell.

Furthermore, searching Groups III, V and VII together would impose a serious and undue burden. In the instant case, prior art searches of transgenic animal or a method of regulating gene expression by downregulation or a method of testing a drug function or a method of controlling the ability of a cell to be recognized immunologically are not coextensive. Search of each of these inventions would require different key word searches of the particular limitations of the transgenic animal and the distinctive steps required by each method. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of any of Groups III, V and VII together.

10. Groups IV, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups IV, V and VI are relied upon as above. In the instant case the different inventions are not disclosed as capable of use together and have different functions. Group IV functions to provide a method of making a transgenic animal and is distinguished by particular method steps that require sex cells and subsequent fertilization procedures. Group V functions to provide a method of reducing the expression of a target gene in any cell. Group VI functions to provide a method of

testing the function of a drug in the absence of a particular polypeptide and is distinguished by particular steps related to the administration of drugs to be tested and determining function.

Furthermore, searching any of Groups IV, V and VI together would impose a serious and undue burden. In the instant case, prior art searches of a method of making a transgenic animal or a method of regulating gene expression in a cell or a method of testing a drug function are not coextensive. Search of each of these inventions would require different key word searches for the particular steps required by each method that would not be required by a search of the other methods. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of any of Groups IV, V and VI together.

11. Groups IV, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups IV, VI and VII are relied upon as above. In the instant case the different inventions are not disclosed as capable of use together and have different functions. Group IV functions to provide a method of making a transgenic animal and is distinguished by particular method steps that require sex cells and subsequent

fertilization procedures. Group VI functions to provide a method of testing the function of a drug in the absence of a particular polypeptide and is distinguished by particular steps related to the administration of drugs to be tested and determining function. Group VII functions to provide a method of controlling the ability of a cell to be recognized immunologically by repressing the expression of an siRNA in a cell.

Furthermore, searching any of Groups IV, VI and VII together would impose a serious and undue burden. In the instant case, prior art searches of a method of making a transgenic animal or a method of regulating gene expression in a cell or a method of controlling the ability of a cell to be recognized immunologically are not coextensive. Search of each of these inventions would require different key word searches for the particular steps required by each method that would not be required by a search of the other methods. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of any of Groups IV, VI and VII together.

12. Group I is further restricted as follows.

13. Group I contains claims to the following patentably distinct inventions wherein the polynucleotide construct is under control of a repressible promoter or an inducible promoter. These promoters are considered to be patentably distinct because they are

not disclosed as capable of use together and have different functions. The function of a repressible promoter is to repress, or down-regulate, RNA transcription from a nucleic acid template. The function of an inducible promoter is to induce, or up-regulate, RNA transcription from a nucleic acid template. Moreover, prior art searches of inducible and repressible promoters are not co-extensive in that they require different searches for the functional requirements of each promoter. A search of both types of promoters together would place an undue and serious search burden on the Examiner.

Therefore, if Applicant elects Group I for prosecution on the merits, Applicant is required to elect a single invention that is an inducible or repressible promoter as identified above. Applicant's election of Group I is also subject to a further restriction between the patentably distinct repressible promoters that are regulated by I) tet repressor or ii) lacI repressor as listed in claims 6-8. Each of the different promoters above, operates to repress or induce gene expression in response to a particular and

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14. Groups II and

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regulating gene expression in a cell requires a polynucleotide construct that is under

control of a regulatable promoter that is a repressible promoter or an unregulatable promoter that is a constitutive promoter (V). These promoters are considered to be patentably distinct because they are not disclosed as capable of use together and have different functions.. The function of a repressible promoter is to repress, or down-regulate, RNA transcription from a nucleic acid template. The function of a constitutive promoter is to express, constitutively, an RNA transcript from a nucleic acid template. Constitutive promoters are known in the art to be unregulatable promoters. Moreover, prior art searches of constitutive and repressible promoters are not co-extensive in that they require different searches for the functional requirements of each promoter. A search of both types of promoters together would place an undue and serious search burden on the Examiner.

Furthermore, if Applicant elects Group II for prosecution on the merits, Applicant is requested to elect a single invention that is a constitutive or a repressible promoter as identified above. Additionally, if electing V, Applicant is required to elect between patentably distinct methods of treating hyperproliferative disorders, hyperthyroidism and hypersecretion defects as set forth in claims 79, 82 and 83 respectively. If electing Group V and hyperproliferative disorders, Applicant will be further required to elect a patentably distinct cancer (see below).

15. Claim 68 is subject to an additional restriction since it is not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely

related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claim 68 specifically claims 35 different oncogenes, the expression of which is regulated by a polynucleotide expression construct of claim 1 that expresses an siRNA. Each different oncogene, that is targeted by the claimed siRNA, is considered to be unrelated, since each oncogene sequence claimed is structurally and functionally independent and distinct and will be regulated by a structurally and functionally independent siRNA for the following reasons: each siRNA sequence has a unique nucleotide sequence, each siRNA sequence targets a different and specific region of a different oncogene, and absent evidence to the contrary, each siRNA, upon recruiting DICER to initiate RNA interference, is expected to functionally modulate (increase or decrease) the expression of each different oncogene to varying degrees. As such the

Markush/genus of oncogenes listed in claim 68, that are regulated by the instantly claimed siRNA expression constructs, are not considered to constitute a proper genus, and are therefore subject to restriction.

Furthermore, a search of more than one (1) of the oncogenes in claim presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed siRNA sequences that are required to regulate the expression of one of the different oncogenes. Accordingly, if Applicant elects group V for prosecution on the merits, Applicant is required to elect one (1) target oncogene from claim 68, the expression of which will be regulated in the claimed method. Note that this is not a species election.

16. Claims 3, 9, 11-14, 20, 26, 30, 36, 39, 70, 75 and 81 are subject to an additional restriction since each is not considered to be a proper genus/Markush. (See MPEP 803.02 as applied above).

a) repressible promoters that are from one of the genes listed in claim 9.

b) promoters that are inducible by the compounds listed in claims 11 and 12 or that are one of the promoters that are listed in claims 13 or 14 (including an election of one of the compounds listed in claims 11 or 12 that is a compound that induces the elected promoter).

c) vectors that comprise polynucleotides as listed in claims 3, 20, 30, 36 and 39

d) tissue specific promoters listed in claim 26

e) agents listed in claim 70

f) transplantation antigens listed in claim 75

h) disease conditions that are cancers listed in claim 81

Applicant is requested to elect a single patentably distinct embodiment of each category identified above along with an election of the Group of their invention for prosecution on the merits (including identification of all claims readable thereon).

17. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of sequence and literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba